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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/608,825 | 06/24/2003 | David J. Yonce | 279.669US1 | 7977 |

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EXAMINER

FLORY, CHRISTOPHER A

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3762

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--|--|
| Office Action Summary | Application No. 10/608,825 | Applicant(s) YONCE, DAVID J. | |
| | Examiner Christopher A. Flory | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings were received on 16 June 2006. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-13 and 15-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gauglitz (US Patent 5,231,990).

Regarding claims 1,2, 15 and 17, Gauglitz'990 discloses a device (Figure 1, ECG monitor system 10) comprising a first, second and third input terminals (Fig. 2, analog input channels 102) with attached first, second, and third external electrodes (ECG electrode leads 12); a depolarization detector circuit (any of the ASICs 100 as disclosed, or a combination thereof, can be configured to function as a three- to fifteen-lead ECG monitoring system; column 1, line 60 through column 2, line 19; column 3, lines 3-53; column 13, lines 4-14); at least one pace pulse detector circuit capable of detecting at least one of pace pulse amplitude or pulse width (Fig. 2, pacer detect circuit 122; column 16, lines 1-43); and a logic circuit coupled to the pace pulse detector circuit (controller 24; column 3, lines 21-25).

Regarding claims 8 and 19, Gauglitz'990 discloses an ECG monitor system (10) comprising one or a combination of any number of ASICs (100) which can be configured as a depolarization detector circuit, pace pulse detector circuit (122), pacer delay circuit (130), or pacer blanking circuit (132) connected by a controller 24. As disclosed, the Gauglitz'990 device is capable of performing the methods claimed in the instant application including: receiving heart signals from the external electrodes; detecting respective electric fields (polarity) of at least one first and at least one second pacing pulses delivered to the heart (column 15, lines 51-68); detecting at least one of pace pulse amplitude, pulse width, polarity or time difference between the pace pulse and a corresponding heart depolarization (column 16, lines 1-43); and classifying the pace pulses by location in either an atrium or a ventricle based upon the signal polarities or one of the other electrical or physiologic computations herein described. It is understood that the clocking device implemented in the pacer delay and blanking circuits would also be capable of being implemented by the controller (24) to measure the time difference between the trailing edge of a pacing pulse as defined by the comparators in the pace detector circuit and the leading edge of a ventricular depolarization (R-wave) as recognized by the ASIC configured as a depolarization detector circuit. Therefore, the instant application does not distinguish over the Gauglitz'990 system.

Regarding claims 3-6, 9-12, and 18, Gauglitz'990 shows the three electrodes being arranged with first electrode near the right arm (RA), second electrode near the left arm (LA), and third electrode below the heart or on the left leg (LL) (Fig. 1); such

that vectors I, II and III are defined between the electrodes with first electrode negative with respect to the second and third electrodes, the second electrode positive with respect to the first and negative with respect to the third electrode, and the third electrode positive with respect to the first and second electrodes (column 7, line 35 through column 9, line 2; Tables 1 and 2). This 3-lead arrangement of surface EKG electrodes is well known to those in the art and is commonly referred to as Einthoven's triangle.

Specifically regarding claims 4-6 and 12, the polarity recorded along any of the claimed leads is governed by elementary properties of physics inherent in the physical placement of the external electrodes and the spatial orientation of the implanted bipolar pacing leads being monitored by the system. Thus, given the placement and orientation of the atrial and ventricular pacing leads as they are disclosed in the instant application, the polarity of leads I, II, and III in the Gauglitz'990 device would behave identically given identical input criteria, and is therefore considered capable of assigning a pace pulse to either an atrial or a ventricular lead based upon the polarity read across leads II and III (column 15, lines 51-68). Therefore the claims of the instant application do not distinguish over the device disclosed in the Gauglitz'990 patent.

Regarding claims 7, 13, 16, and 20, the system of Gauglitz'990 as disclosed can be configured to consist of a pace pulse detector circuit and pacing blanking circuit (column 13, line 56 through column 14, line 20) working parallel to a depolarization detection circuit connected to the same controller such that the system would be capable of marking a detected pacing pulse, marking a detected depolarization, and

determining whether that depolarization has occurred within a predetermined time period of the pace pulse (e.g. within the timeframe of the pacer blanking circuit), and then make use of that information to assign a location classification to the marked pace pulse (column 15, line 23 through column 16, line 42).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 14 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gauglitz'990 in view of Johnson and Swartz (*A Simplified Approach to Electrocardiography*, 1986, Chapters 3 and 5).

Gauglitz'990 discloses the current invention substantially as claimed except for displaying an indication of the location classification in correspondence with at least one of the first and second pace pulses on the electrocardiogram. In the same field of

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endeavor, the Johnson and Swartz reference teaches an electrocardiogram displaying the axial location classification of a given electrical signal originating within the heart for the advantages of chart readability and diagnosing electrocardiographic abnormalities based on axial deviations (Johnson and Swartz, *A Simplified Approach to Electrocardiography*, pp. 23-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the indication of a given (pacing) signal's location on the EKG readout of the Gauglitz'990 device for the same advantages of chart readability and diagnosis of functional abnormalities. (motivation to combine provided by Johnson and Swartz, *A Simplified Approach to Electrocardiography*, pp. 23-25).

Response to Arguments

7. Applicant's arguments filed 16 June 2006 have been fully considered but they are not persuasive. Applicant argues that Gauglitz does not disclose assigning a first location assignment to the first pace pulse and a second location to the second pace pulse using at least in part the polarity information about the pace pulses. Applicant further argues that Gauglitz does not disclose classifying the pace pulses into distinct classes using at least one of the amplitude, pulse width, polarity and time difference, and that there is no inference to "location" of pace pulses. Finally, applicant argues that Johnson and Swartz does not disclose all elements in the claims 14-21 and fails to disclose determining or displaying locations of pace pulses.

8. Regarding the argument that Gauglitz does not disclose assigning location assignments to the first and second pace pulses using at least in part polarity information about the pace pulses, Examiner maintains the original position as set forth in the record that Gauglitz constitutes a proper rejection under 35 U.S.C. 102(b) of claims 1-13 and 15-20. Gauglitz does disclose, as pointed out above, a device which calculates the polarity of a plurality of pacing pulses. In order for vector calculations to be performed in the lead summing network (112) using this data, the amplitude and polarity measured from each electrode must inherently be stored, either temporarily or permanently, in the ASIC unit and compared. As such, a first memory location assignment must be given to the first pace pulse and a different or second memory location assignment must be given to the second pace pulse, the two then being compared based at least in part on polarity to arrive at a vector sum output.

In the alternative, this limitation within the claim constitutes functional language within an apparatus claim, and is not given patentable weight so long as it does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

It should be understood that this rejection has been made in light of a reasonable interpretation of the language set forth in the claims.

9. Regarding the argument that Gauglitz does not disclose classifying the pace pulses into distinct classes using at least one of the amplitude, pulse width, polarity and time difference, Examiner maintains the original position as set forth in the record that Gauglitz discloses a device which is capable of measuring amplitude, pulse width, time

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difference and polarity. Following the same argument from paragraph 8 above, assigning temporary or permanent locations to each pace pulse data point for the purpose of vector calculation constitutes classifying each of the data points into its own class based on any or all of the measurable variables set forth, particularly polarity. It is further noted that the disclosure of vector calculations does impart a degree of "location" to the pace pulses, as location is a critical basis of all vector calculations.

In the alternative, this limitation within the claim constitutes functional language within an apparatus claim, and is not given patentable weight so long as it does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

It should be understood that this rejection has been made in light of a reasonable interpretation of the language set forth in the claims.

10. Regarding the argument that Johnson and Swartz does not disclose all elements in the claims 14 and 21 and fails to disclose determining or displaying locations of pace pulses, Examiner maintains that, for the stated reasons of record, the rejection under 35 U.S.C. 103(a) based on Gauglitz in view of Johnson and Swartz is proper.

In response to applicant's argument that the present application describes determining the location of pace pulses such that a display strip can be conveniently annotated for a physician, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's arguments against the Johnson and Swartz reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

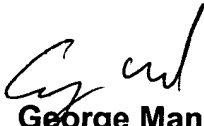
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory
5 September 2006


George Manuel
Primary Examiner